

CLAIM AMENDMENTS

1 1. (Currently amended) A pharmaceutical formulation,
2 packaged into a sachet and administered orally after dispersing in
3 water at therapeutic doses which comprises:

4 (a) alendronate microparticles coated with a polymer
5 soluble at a gastric pH of 1 to 4, but insoluble at a salivary pH
6 of 6 - 7.5, and uncoated alginic acid or sodium alginate or
7 admixtures thereof in an amount therapeutically effective to
8 prevent esophageal reflux, heartburn and esophagitis in a patient
9 taking alendronate, where

10 (b) alendronate dissolves in 900 ml 0.1 N HCl at the rate
11 of not less than 85% of within 30 minutes at the range of pH 1 - 4,

12 (c) the dispersion in a glass of 250 ml. water at the
13 degree of 25°C contains no dissolved alendronate at pH 6 - 7.5 or
14 at the most 10% w/v of alendronate dissolved in 3 minutes.

1 2. (Original) The pharmaceutical formulation as claimed
2 in claim 1, comprises lubricants, diluents, flavors and sweeteners
3 or their mixture thereof.

1 3. (Previously presented) The pharmaceutical formulation
2 as claimed in claim 2, where in the diluent is selected from the
3 group consisting of lactose and microcrystalline cellulose or
4 admixtures thereof.

1 4. (Previously presented) The pharmaceutical formulation
2 as claimed in claim 2, where in the sweetener is selected from the
3 group consisting of aspartame, potassium acesulfame, monoammonium
4 glycyrrhizinate, sodium saccharine, sucrose and polyols, used alone
5 or in combination.

1 5. (Previously presented) The pharmaceutical formulation
2 as claimed in claim 1, where in the polymer is selected from the
3 group consisting of polymethacrylates, polyvinyl acetate
4 diethylaminoacetate and poly butyl methacrylate / 2-dimethylamino-
5 ethyl methacrylate/methyl methacrylate copolymers or their mixtures
6 thereof.

1 6. (Previously presented) The pharmaceutical formulation
2 as claimed in claim 1, where in the polymer is Poly(butyl
3 methacrylate, (2-dimethyl aminoethyl) methacrylate, methyl
4 methacrylate) in a ratio of 1:2:1.

1 7. (currently amended) The pharmaceutical formulation as
2 claimed in claim 1, which is dispersed in a glass of 250 ml water
3 at the degree of 25°C at pH 6 - 7.5, and which contains
4 alendronate in between 0.001% w/v - 3% w/v.

1 8. (Previously presented) The pharmaceutical formulation
2 as claimed in claim 1 where in the alendronate is alendronate
3 monosodium trihydrate.

1 9. (Currently amended) The pharmaceutical formulation as
2 claimed in claim 1, which is dispersed in a glass of 250 ml. water
3 at the degree of 25°C at pH 6 - 7.5, and which contains uncoated
4 alginic acid or sodium alginate or their mixtures in between 0.001%
5 w/v - 2% w/v.

1 10. (Currently amended) A pharmaceutical formulation,
2 which is packaged into a sachet and orally administered after
3 dispersing in water, which ~~consists essentially of~~ comprises:
4 alendronate microparticles coated with a polymer insoluble at a
5 salivary pH 6 to 7.5, but soluble at a gastric pH of 1 to 4 wherein
6 the polymer comprises polybutyl methacrylate,
7 (2-dimethylaminoethyl)methacrylate and methyl methacrylate in a
8 1:2:1 ratio; uncoated alginic acid or sodium alginate or admixtures
9 thereof in an amount therapeutically effective to prevent
10 esophageal reflux, heartburn and esophagitis in a patient taking
11 alendronate; sucrose and sodium saccharine as sweeteners;
12 microcrystalline cellulose as diluent; and colloidal silica as a
13 lubricant, wherein the alendronate dissolves in 900 ml of 0.1N HCl
14 at a rate of not less than 85% within 30 minutes at a pH of 1 to 4,

15 and wherein the resulting dispersion in water at 25°C contains
16 either no dissolved alendronate at a pH of 6 to 7.5, or at most 10%
17 w/of dissolved alendronate after 3 minutes.